tiated. This national strategy will provide for an effective distribution, application, and utilization of limited Federal, State, and local resources.

References

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LETTER TO THE EDITOR

FDA's Center for Biologics Evaluation and Research Comments on the Report of the Expert Panel

The Center for Biologics Evaluation and Research, Food and Drug Administration (FDA), welcomes the opportunity to comment on the article entitled "Report of an Expert Panel on the Public Health Laboratory Role in Early Intervention and Treatment of Human Immunodeficiency Virus Infections," appearing in this issue of *Public Health Reports*. The report was first released in July 1990 by the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD).

The report calls for directed and expanded activities related to control of the HIV epidemic. ASTPHLD should be applauded for taking a leadership role in addressing this need, and the general finding in the report that provision of a wide spectrum of laboratory services will be critical to this effort is correct. It is necessary, however, to provide clarification of two points which were raised in the report.

First, the report criticizes the regulation of AIDS-related tests as licensed biological products rather than as medical devices, on the premise that review of these products as devices would be either less stringent with respect to required evidence of safety and efficacy or more rapid. However, the nature of the review process in this product area is not dictated by the type of application required, but rather by the need for high standards of consistency and accuracy for tests with major health significance, such as these. Also, in many cases, AIDS-related tests are used not only for clinical diagnosis, but also to screen blood donated for transfusion. The FDA recognizes the continuing public concern about the safety of the blood supply and, for this reason, also feels that it is appropriate to set high standards for approval of these tests.

Compared with laws on medical devices, laws on biologics do provide the FDA with additional tools for maintaining product standards. Among the safeguards is authority to require lot-by-lot testing and release to ensure that products meet appropriate standards.

Considering the need for extensive validation of manufacturing and clinical performance of these kits, the FDA has been expeditious in its reviews. The first kit for detection of HIV was licensed within 1 year of the discovery of HTLV-III, the virus that causes AIDS, and within 7 months of the first license application. Since that time, many additional products have been licensed in a timely fashion, including tests for HTLV-I. Apparent delays in licensing are often due to problems in manufacturing consistency, deficiencies in clinical data, or controversy over medical claims, issues which are not discussed in the public domain.

A second inaccuracy in the report is the statement that "monoclonal antibodies for immunophenotyping of CD4 and CD8 lymphocytes are presently restricted by the FDA for research purposes only." In fact, these monoclonal antibodies are marketed as medical devices subject to the medical device regulations.

The report also calls for increased cooperation among various agencies. The FDA agrees that cooperation among all institutions involved with public health is important in dealing with the AIDS epidemic. Indeed, ASTPHLD has an ongoing formal relationship with the Public Health Service through the Centers for Disease Control, which has primary responsibility for epidemic control. Additional cooperative roles are certainly possible and should be encouraged.

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